IN THE UNITED STATES DISTRICT COURT FOR THE WESTERN DISTRICT OF NORTH CAROLINA CHARLOTTE DIVISION CIVIL ACTION NO. 3:09 CV 210-RJC-DSC

MARY CLEO COUICK,)
)
Plaintiffs,)
)
v.)
) MEMORANDUM AND RECOMMENDATION
WYETH, INC., ACTAVIS INC.,	
ACTAVIS ELIZABETH, LLC,)
SCHWARZ PHARMA, INC., and)
PLIVA USA, INC.,)
)
Defendants.)
)

THIS MATTER is before the Court on Defendants' "Joint Motion to Dismiss" (document #77) filed July 14, 2011, and the parties' associated briefs and exhibits (documents ## 77-80).

This matter has been referred to the undersigned Magistrate Judge pursuant to 28 U.S.C. § 636(b)(1)(B), and is now ripe for the Court's consideration.

Having fully considered the arguments, the record, and the applicable authority, the undersigned respectfully recommends that Defendants' Motion to Dismiss be granted, as discussed below.

I. PROCEDURAL AND FACTUAL BACKGROUND

The relevant facts are straightforward. Plaintiff alleges that between July 2002 and April 2007, her physician prescribed Reglan, manufactured by former Defendants Wyeth Inc. and Schwarz Pharma, Inc., or metoclopramide, a generic bioequivalent of Reglan manufactured by Defendants

¹On March 8, 2010, the Honorable Robert J. Conrad, Jr., the District Judge to whom this case is assigned, granted Wyeth Inc. and Schwarz Pharma, Inc.'s Motion for Summary Judgment. <u>Couick v. Wyeth, Inc.</u>, 691 F.Supp.2d 643, 645 (W.D.N.C. 2010)

Actavis Inc./Actavis-Elizabeth LLC (hereinafter "Actavis") and Pliva USA, Inc. to treat her reflex esophagitis. Plaintiff further alleges that overexposure to those medicines caused her to develop tardive dyskinesia.

On May 28, 2009, Plaintiff filed her Complaint, which states claims against Defendants under state law tort theories of negligence, breach of undertaking special duty, misrepresentation, negligent and intentional infliction of emotional distress, unfair trade practices, breach of warranties, fraud, and failure to warn. Plaintiff contends that Defendants' labeling should have included stronger warnings about the association between long-term exposure to metoclopramide and movement disorders such as tardive dyskinesia.

It is the law of this case that "[w]hile the [P]laintiff's claims are masked in various legal theories, they are premised on a single claim of product liability... [e]ach of these claims is based on the premise that [Defendants] are liable for Couick's physical condition because they failed to adequately warn Couick's doctors about the dangers of metoclopramide." Couick, 691 F.Supp.2d at 645.

On July 14, 2011, Defendants moved to dismiss under Fed. R. Civ. P. 12(b)(6), contending that in <u>PLIVA</u>, <u>Inc. v. Mensing</u>, ___ U.S. ___, 131 S. Ct. 2567 (2011), "the United States Supreme Court clearly, unequivocally, and without exception, declared that state-law failure-to-warn claims against generic pharmaceutical manufacturers are preempted." Defendants' "Reply ..." at 1 (document #80).

Defendants' Motion to Dismiss has been fully briefed and is ripe for disposition.

II. DISCUSSION OF CLAIM

In reviewing a Rule 12(b)(6) motion, "the court should accept as true all well-pleaded

allegations and should view the complaint in a light most favorable to the plaintiff." Mylan Labs., Inc. v. Matkari, 7 F.3d 1130, 1134 (4th Cir. 1993). The plaintiff's "[f]actual allegations must be enough to raise a right to relief above the speculative level." Bell Atlantic Corp. v. Twombly, 550 U.S. 544, 555 (2007). "[O]nce a claim has been stated adequately, it may be supported by showing any set of facts consistent with the allegations in the complaint." Id. at 563. A complaint attacked by a Rule 12(b)(6) motion to dismiss will survive if it contains "enough facts to state a claim to relief that is plausible on its face." Ashcroft v. Iqbal, 129 S. Ct. 1937, 1960 (2009), quoting Twombly, 550 U.S. at 570. "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." Id. at 1949.

In <u>Iqbal</u>, the Supreme Court articulated a two-step process for determining whether a complaint meets this standard. First, the court identifies allegations that, because they are no more than conclusions, are not entitled to the assumption of truth. 129 S. Ct. at 1951. "Threadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice." <u>Id.</u> at 1951 (allegation that government officials adopted challenged policy "because of" its adverse effects on protected group was conclusory and not assumed to be true), <u>citing Twombly</u>, 550 U.S. at 554-55. Although the pleading requirements stated in "Rule 8 [of the Federal Rules of Civil Procedure] mark[] a notable and generous departure from the hyper-technical, code-pleading regime of a prior era ... it does not unlock the doors of discovery for a plaintiff armed with nothing more than conclusions." Id. at 1950.

Second, to the extent there are well-pleaded factual allegations, the court should assume their truth and then determine whether they plausibly give rise to an entitlement to relief. <u>Id.</u> at 1951. "Determining whether a complaint contains sufficient facts to state a plausible claim for relief "will

... be a context-specific task that requires the reviewing court to draw on its judicial experience and common sense." <u>Id.</u> at 1950. "Where the well-pleaded facts do not permit the court to infer more than the mere possibility of misconduct, the complaint has alleged-but it has not 'show[n]'-'that the pleader is entitled to relief," and therefore should be dismissed. <u>Id.</u>, <u>quoting</u> Fed. R. Civ. P. 8(a)(2). In other words, if after taking the complaint's well-pleaded factual allegations as true, a lawful alternative explanation appears a "more likely" cause of the complained of behavior, the claim for relief is not plausible. <u>Id.</u> at 1951-52.

On June 23, 2011, the United States Supreme Court issued its decision in Mensing, _____U.S. at ____, 131 S. Ct. at ____. The Supreme Court reversed the Fifth and Eighth Circuit Courts of Appeals, both of which had concluded that claims identical to those presented by Plaintiff here are not preempted. After analyzing the duties under state and federal law, the Court concluded that it was impossible for generic drug manufacturers to comply with both. As the Court noted, "it [is] not lawful under federal law for the Manufacturers to do what state law required of them." Id. The Court found that generic drug companies violate federal law if they change their labeling to satisfy a state-law duty to warn. Id. The Supreme Court held that state law failure to warn claims are preempted and reversed the lower courts. Id.

III. ORDER

IT IS ORDERED that all further proceedings in this action, including <u>all</u> discovery, are STAYED pending the District Judge's ruling on this Memorandum and Recommendation and Order.

IV. RECOMMENDATION

FOR THE FOREGOING REASONS, the undersigned respectfully recommends that

Defendants' "Joint Motion to Dismiss" (document #77) be **GRANTED** and that the Complaint be **DISMISSED WITH PREJUDICE**.

V. NOTICE OF APPEAL RIGHTS

The parties are hereby advised that, pursuant to 28 U.S.C. §636(b)(1)(c), written objections to the proposed findings of fact and conclusions of law and the recommendation contained in this Memorandum must be filed within fourteen (14) days after service of same. Failure to file objections to this Memorandum with the District Court constitutes a waiver of the right to de novo review by the District Judge. Diamond v. Colonial Life, 416 F.3d 310, 315-16 (4th Cir. 2005); Wells v. Shriners Hosp., 109 F.3d 198, 201 (4th Cir. 1997); Snyder v. Ridenour, 889 F.2d 1363, 1365 (4th Cir. 1989). Moreover, failure to file timely objections will also preclude the parties from raising such objections on appeal. Thomas v. Arn, 474 U.S. 140, 147 (1985); Diamond, 416 F.3d at 316; Page v. Lee, 337 F.3d 411, 416 n.3 (4th Cir. 2003); Wells, 109 F.3d at 201; Wright v. Collins, 766 F.2d 841, 845-46 (4th Cir. 1985); United States v. Schronce, 727 F.2d 91 (4th Cir. 1984).

The Clerk is directed to send copies of this Memorandum and Recommendation and Order to counsel for the parties; and to the Honorable Robert J. Conrad, Jr.

SO RECOMMENDED AND ORDERED.

Signed: August 12, 2011

David S. Cayer

United States Magistrate Judge